Alabama Medicaid Agency

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CAROL HERRMANN STECKEL, MPH
Commissioner

September 28, 2007

Dear Pharmaceutical Manufacturer:

This correspondence is to provide you with formal written notification of an upcoming meeting of the Alabama Medicaid Pharmacy & Therapeutics (P&T) Committee, to be held on **Wednesday, November 14, 2007**. This meeting may involve review of one or more of your company's drug products. Please note: this meeting will be held at the Alabama State Capitol Auditorium located in Montgomery, Alabama, and will begin at 9:00 a.m. All meetings of this committee are open to the public.

The following is a list of drug classes for review at this meeting:

Drug Class REVIEWS
1. Alzheimer's Agents AHFS 120400 – Parasympathomimetic (Cholinergic) Agents (to include Aricept®, Aricept ODT®, Razadyne®, Razadyne ER®, Exelon®, Exelon Patch®, Cognex® only) AHFS 289200 – Miscellaneous Central Nervous System Agents (to include Namenda® only)
2. AHFS 281604 – Antidepressants
3. Cerebral Stimulants/Agents used for ADHD AHFS 282004 – Amphetamines (to include Adderall®, Adderall XR®, Dexedrine®, Dexedrine Spansule®, Dextrostat®, Vyvanse®, Desoxyn® only) AHFS 282092 – Miscellaneous Anorexigenic Agents and Respiratory and Cerebral Stimulants (to include Focalin®, Focalin XR®, Concerta®, Daytrana®, Metadate CD®, Metadate ER®, Methylin®, Methylin ER®, Ritalin®, Ritalin LA®, Ritalin-SR®, Provigil® only) AHFS 289200 – Miscellaneous Central Nervous System Agents (to include Strattera® only)
4. AHFS 282404 – Anxiolytics, Sedatives and Hypnotics-Barbiturates
5. AHFS 282408 – Anxiolytics, Sedatives and Hypnotics-Benzodiazepines
6. AHFS 282492 – Miscellaneous Anxiolytics, Sedatives and Hypnotics

** Please note that a new drug product must be on the market for a minimum of 6 months from launch date in order to be included in a drug class review.*

As you may be aware, manufacturers whose products are scheduled for review are allowed the opportunity to provide written clinical comments for distribution to the Medicaid P&T Committee members prior to the meeting. For products slated for P&T Committee review, manufacturers are also allowed the opportunity to make brief (no more than 5 minutes) oral summary presentations of their products' clinical data to the Medicaid P&T Committee on the day of the meeting.

Approval for distribution of written clinical comments to P&T Committee members and approval of oral presentation summary submissions are based strictly upon the following guidelines:

Written Comments:

1) All written comments must be mailed to Medicaid's Clinical Contractor, *MedMetrics Health Partners, Attn: AL Medicaid P&T Support (1-800-644-4079); 100 Century Drive; Worcester, MA 01606*, and received no later than **Wednesday, October 24, 2007**. Packages must be properly labeled "*Attn: AL Medicaid P&T Support*" and include the full contact information of the designated manufacturer's point of contact.

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2) Submissions should be limited to one drug product per packet. Manufacturers wishing to provide written comments on more than one drug product must submit a separate packet for each product.
3) **Submissions are limited to 100 pages single-sided (or 50 pages double-sided) and a maximum binder size of 1 inch.**
4) Written comments should be limited to clinical information only and **must not contain any reference to cost or general drug- or disease-specific economic information.**
5) Written comments must be confined to evidence-based clinical information and limited to Food and Drug Administration (FDA)-approved indications covered under Alabama Medicaid Pharmacy benefit and not contain anecdotal content.
6) Submissions are limited to hard-copy written form only (not CD-ROM, e-mail, etc.).
7) Manufacturers must provide **twenty (20) copies of written comments** upon submission to *MedMetrics at the above mentioned contact information.*

Oral Presentation Summaries:

1) Written notification of your intent to make an oral presentation must be mailed to *MedMetrics Health Partners, Attn: AL Medicaid P&T Support (1-800-644-4079); 100 Century Drive; Worcester, MA 01606,* and received no later than **Wednesday, October 24, 2007**. Submissions must be properly labeled "*Attn: AL Medicaid P&T Support*" and include the full contact information of the designated manufacturer's point of contact.
2) Oral presentation summaries should be limited to one drug product per submission. Manufacturers wishing to provide an oral presentation on more than one drug product must submit a separate one-page summary for each product.
3) Oral presentations must also be limited to clinical information only and **must not contain any reference to cost or general drug- or disease-specific economic information.**
4) Oral presentations must be confined to evidence-based clinical information and limited to Food and Drug Administration (FDA)-approved indications covered under Alabama Medicaid Pharmacy benefit and not contain anecdotal content. All statistics identified for discussion must be supported by noting the source from which the information was obtained. This information does not have to be in formal reference form.
5) Submissions are limited to hard-copy written form only (not CD-ROM, e-mail, etc.) and should be clearly labeled as "Oral Presentation Summary".
6) **One (1) copy of a one-page summary** of the material to be presented must be received along with the written notification. (Please note: the presentation summary must be a single-sided document; references, package inserts, and any other information may be submitted but only the summary will be reviewed).

Failure to abide by all of these requirements upon submission will result in a rejection of the clinical comments and/or oral presentation summaries in their entirety. Manufacturers are also encouraged to submit information as soon as possible. Waiting until just days prior to the deadline for submission of these materials may not allow time for corrections and resubmission prior to the deadline. No submissions or resubmissions will be accepted after the designated deadline.

Please refer to the Medicaid website for additional information related to presentations, timelines, clinical comment submissions, and/or submission of volume discounts. Volume discount submissions should not be included in this submission to MedMetrics, as these will not be reviewed by MedMetrics nor forwarded to Alabama Medicaid. If you should have additional questions regarding this notice or if you have received this letter and are no longer the appropriate contact, please notify the Medicaid Pharmacy Program at (334) 353-4582.

Sincerely,

Bakeba R. Thomas

Bakeba R. Thomas, Administrator
Pharmacy Clinical Support Unit